UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARTIN LUTHER KING JR. FEDERAL BLDG. & U.S. COURTHOUSE
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WILLIAM J. MARTINI
JUDGE

LETTER OPINION

May 30th, 2007

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RE: United States v. Undetermined Quantities of Boxes of Articles of Device, et al. (Civ. No. 07-1769)

Dear Counsel:

Presently before the Court is Claimant Shelhigh, Inc.'s ("Shelhigh"), motion to release certain seized items intended for export to Italy and Spain. Also before the Court is Shelhigh's motion to release all seized component parts. Plaintiff United States (the "Government") opposes both motions. For the following reasons, Shelhigh's motions are **DENIED**.

BACKGROUND

On April 16, 2007, the Government filed a Complaint seeking forfeiture *in rem* of certain undetermined quantities of articles of device. The articles of device consisted of cardiovascular, neurological, and general surgery sterile implantable medical devices, including pulmonic and aortic heart valves and pericardial patches that are surgically implanted in patients. The Complaint sought seizure and condemnation of the devices under 21 U.S.C. § 334. In their Complaint, the Government claims that the articles of device are "adulterated" under 21 U.S.C. § 351(h) because the methods and facilities used for their manufacture, packaging, storage, and installation are not in conformity with current good manufacturing practice requirements ("CGMP") under the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-99, and its "Quality System" ("QS") regulations, 21 C.F.R. part 820, *et seq*.

On April 17, 2007, the Court issued a warrant for arrest *in rem* of the articles of device. The Government then seized Shelhigh's entire inventory of implantable medical devices, including component parts. On May 4, 2007, Shelhigh filed an emergency motion for an expedited order to show cause why certain devices should not be released for export to Italy and Spain. The Court granted Shelhigh's request on May 7, 2007.

In their motion, Shelhigh argues that fourteen specific articles of device should be released by the Government for export to Italy and Spain. Shelhigh claims that these devices need not meet the CGMP requirements if they meet the requirements under 21 U.S.C. § 381(e)(1). In addition, in a separately filed motion, Shelhigh asks the Court to order the release of all components seized by the Government. Shelhigh contends that such components are exempted from the CGMP requirements. The Government opposes both requests. Shelhigh's motions are now before the Court.

DISCUSSION

I. Release of Articles of Device Intended for Export Only

Congress enacted the FDCA in 1938. It prohibits "the introduction or delivery for introduction into interstate commerce of any ... device ... that is adulterated...." 21 U.S.C. § 331. A device is "adulterated" if:

> [T]he methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under [21 U.S.C. § 360j(f)(1)]....

21 U.S.C. § 351(h). Section 360j(f)(1) provides that the FDA may promulgate regulations concerning CGMP. *Id.* § 360j(f)(1)(A). The QS Regulations, found at 20 C.F.R. part 820, embody that effort.

A device intended for export, though, is not deemed adulterated if it meets the requirements of 21 U.S.C. § 381. Specifically, § 381(e)(1) provides that:

> [A] ... device ... intended for export shall not be deemed to be adulterated ... if it: (A) accords to the specifications of the foreign purchaser; (B) is not in conflict with the laws of the country to which it is intended for export; (C) is labeled on the outside of the shipping package that it is intended for export; and (D) is not sold or offered for sale in domestic commerce.

21 U.S.C. § 381(e)(1)(A)-(D). This exception, though, does not apply to any device:

> [W]hich does not comply with an applicable requirement of ... [21 U.S.C. § 360e] ... unless, in addition to the requirements of [§ 381(e)(1)] either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under [21 U.S.C. § 382].

21 U.S.C. § 381(e)(2). Section 360e governs "pre-market approval" of devices. *Id.* § 360e. It provides that a Class III device is required to have pre-market approval, unless it is exempt under 21 U.S.C. § 360j(g). *Id.* § 360e(a). Any device that was not in interstate commerce prior to May 28, 1976, is automatically classified into Class III unless it receives an exception from the FDA. *Id.* § 360c(f)(1). Furthermore, § 382 governs "[e]xports of certain unapproved products." *Id.* § 382. Specifically, § 382(f)(1) provides that an unapproved device may not be exported if it "is not manufactured, processed, packaged, and held in substantial conformity with [the CGMP requirements]...." *Id.* § 382(f)(1).

Read together, these provisions create the following rule: an adulterated device may be exported if it meets the four requirements found in § 381(e)(1)(A)-(D); however, this exception does not apply if the product is unapproved unless the product has also received a determination that it is not contrary to public health and safety or meets the CGMP requirements. *See United States v. Themy-Kotronakis*, 140 F. 3d 858, 863 (10th Cir. 1998) ("Moreover, devices that fail to meet the requirements of ... 360(e) (relating to ... premarket approval) are not eligible for export under 381(e), unless the FDA grants an exception."); *United States v. Universal Mgmt. Servs.*, 999 F. Supp. 974, 987 (N.D. Ohio 1997) (holding that "[b]ecause ... Defendants' devices did not comply with applicable premarket approval requirements and Defendants did not request an FDA determination that would allow the exportation of their devices, Defendants cannot qualify for export [under § 381(e)(1)].").

In the present case, Shelhigh concedes that none of its fourteen devices received FDA pre-market approval. Furthermore, Shelhigh did not begin producing these devices until 1998. Therefore, to export the devices, Shelhigh must either receive a determination from the FDA that

exportation is not contrary to public health or must demonstrate that its devices satisfy CGMP. Here, Shelhigh does not contend that it received any FDA determination as to the devices' safety. Accordingly, Shelhigh must satisfy the CGMP requirements to export the items. In this regard, the burden of proof is on Shelhigh. *See United States v. Columbus Country Club*, 915 F.2d 877, 882 (3d Cir. 1990); *United States v. Articles of Drug*, 745 F.2d 105, 113 (1st Cir. 1984) (citing *United States v. Allan Drug Corp*., 357 F.2d 713, 718 (10th Cir. 1966)); *United States v. 76,552 Pounds of Frog Legs*, 423 F. Supp. 329, 337 (S.D. Tex. 1976). If Shelhigh meets this burden, it must then satisfy the four elements under § 381(e)(1) to export the devices. *See* 21 U.S.C. § 381(e)(2) (noting that § 381(e)(1) "does not apply to any device ... unless, *in addition to the requirements of paragraph [§ 381(e)(1)]*," the device received a determination from the FDA or meets CGMP) (emphasis added).

The Court, though, cannot determine whether the devices satisfy CGMP without a hearing on the merits. Here, the Government seized the devices pursuant to 21 U.S.C. § 334. Once items are seized pursuant to this section, the Government is entitled to maintain seizure of the items until it hears the matter on the merits of the claim. *See, e.g., United States v. Proplast II*, 946 F.2d 422, 423 (5th Cir. 1991). Furthermore, § 334(d) precludes any disposition of the seized articles prior to the entry of a decree of condemnation. *United States v. 38 Cases*, 369 F.2d 399, 400 (3d Cir. 1966). This hearing must be held before a jury if Shelhigh so requests. 21 U.S.C. § 334(b). However, to the extent possible, this Court may determine certain issues as a matter of law based on undisputed facts. *See* Fed. R. Civ. P. 50, 56; *United States v. Articles of Drug,* 745 F.2d 105, 111-12 (1st Cir. 1984).

Since a hearing on the merits is required, Shelhigh's motion seeking release of items intended for export only is denied The Court is mindful, though, of the continuing harm suffered by Shelhigh while its devices remain in the Government's possession. Therefore, the Court shall hold this hearing as soon as possible. In the interim, the Court suggests that the parties continue to engage in dialogue with the goal of resolving this dispute expeditiously. Submission of the dispute to mediation might also be helpful.

II. Release of Components

Next, Shelhigh asks the Court to order the release of all component parts seized by the Government. It relies on 21 C.F.R. § 820.1(a)(1) to argue that the QS regulations do not apply to manufacturers of components. However, this provision applies to manufacturers that only produce component parts. It does not apply to a company, such as Shelhigh, that is a finished device manufacturer. Therefore, Shelhigh's reliance on § 820.1(a)(1) is unfounded. Accordingly, its request for immediate release of the components is denied.

CONCLUSION

For the foregoing reasons, Shelhigh's motion to release those products intended for export only is **DENIED**. A hearing on the merits regarding their seizure is required.

Furthermore, Shelhigh's request for release of component parts is **DENIED**. An appropriate Order accompanies this Letter Opinion.

s/William J. Martini

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William J. Martini, U.S.D.J.